

**III. Priority Document**

A certified copy of the priority document is presented with a claim for priority.

**IV. Specification**

It is believed that the addition to the specification of a brief description of Figures 8-12 addresses the Examiner's objection to the disclosure. The Examiner's assistance in identifying these minor discrepancies is appreciated.

**V. Double Patenting**

The applicants have attached a terminal disclaimer to overcome the Examiner's obviousness-type double patenting rejection with regard to claims 3, 5, 24 and 26.

**VI. Claim Rejections**

With respect to independent claim 24, the applicants respectfully submit that the subject matter claims differs from the art taught in Caro.

It is respectfully submitted that claim 24 recites a stent for insertion into an intact vessel, i.e., a naturally occurring vessel in the body. Such a stent would normally be deployed by being moved along inside a vessel when in a collapsed condition to the site, and then expanded to hold the vessel open for flow (see page 1 lines 9 to 14 to the present application). Caro, on the other hand, is concerned with a vascular prosthesis, i.e., a length of hollow tubing (see the title, the claims, and page 5, lines 28-32 of Caro). The tubing in Caro is made of an artificial material, typically a biocompatible polymer such as polypropylene (see page 6, lines 4-5). The prosthesis is designed to be used to provide an artificial flow passage in order to bypass a blockage in a natural vessel, such as blockage 7 in artery 6 shown in figure 6, bypassed by the prosthesis 1.

While the applicants agree with the Examiner that there is an isolated statement on page 6 lines 6-10 of Caro that the prosthesis tubing may be supported by a stent, the applicants respectfully disagree with the Examiner that such a device, consisting of the combination of the hollow prosthesis tubing and the stent ("the stented tubing"), could itself be used as a stent and placed inside a natural vessel. The applicants submit that there is no basis whatsoever in Caro for concluding that the stented tubing would be capable of the use proposed by the Examiner. In the absence of a clear disclosure of this capability, the Examiner's anticipation rejection is not justified.

Further, claim 24 clearly requires that the supporting portion of the stent is of a shape and/or orientation which imposes a non-planar curve on the vessel. Conversely, Caro discloses a stent that prevents collapse or kinking of a prosthesis that already has a non-planar shape (see page 5, line 32 to page 6, line 4). There is no disclosure that such stented tubing would be capable of imposing a non-planar curve on a natural vessel. The Examiner argues that the stented tubing “would inherently impose a shape on a vessel it is inserted into because it is designed to be rigid enough to prevent kinking or collapse.” However, there is no teaching that rigidity sufficient to prevent kinking or collapse would also be sufficient to impose a new shape on a natural vessel. Also, there is no teaching of how such a stented tubing would have to fit, in terms of relative size, in a natural vessel in order to impose its shape thereon. This is simply not a consideration for a vascular prosthesis which does not have to fit inside a vessel.

Thus, there is no disclosure that the stented tubing of Caro could impose a non-planar shape on a natural vessel. It is respectfully submitted that the Examiner does in fact seem to concede this point on page 4 of the Office Action wherein he states that “Alternatively, one reading Caro may come to the conclusion that Caro fails to meet the shape imposition requirement as claimed.”

The Examiner has also rejected independent claim 24 as being obvious over Caro alone. However, there is no hint or suggestion in Caro that it would be desirable to devise a stent that imposes a non-planar shape on an intact, natural, vessel in a body of a living being. Caro is concerned with non-planar prosthesis, i.e., an artificial vessel having a special “non-planar” shape. The present invention departs significantly from that idea to the concept of effectively causing an intact vessel to adopt a non-planar shape. This concept of imposing non-planarity on an intact vessel is not remotely suggested in Caro. Accordingly, the Examiner’s obviousness argument is based on the use of impermissible hindsight.

The present invention involves a significant departure from the teaching of an artificial prosthesis having a non-planar curve, as known from Caro, to the idea of imposing a non-planar curve on a natural vessel. The Examiner’s interpretation of Caro (or the claim limitations of the pending claims) is strained and not a fair interpretation. It is therefore respectfully submitted that claim 24 and claims 3, 5, 6, 12-16, 25-31 dependent on claim 24 define over Caro, whether it is considered on its own under §§102 or 103, or in combination with any of the remaining art of record.

The Examiner has also rejected independent claim 24 as being obvious over Caro in view of Fischell. While the Examiner correctly states that Caro may not meet the shape imposition requirement claimed in the present application (i.e., that if the stented tubing mentioned at page 6, lines 6-10 of Caro were inserted into a vessel, it would not impose a shape as required by the present application), the Examiner is of the opinion that Fischell discloses a stent designed to support and prevent the collapse of blood vessels, as required in Caro, and it would therefore have been obvious to use such a stent to prevent collapse and kinking of the tube in the manner suggested in Caro. As such, the Examiner believes that this combination would provide the shape imposition requirement claimed. However, this combination of Caro and Fischell merely amounts to a proposal to use a particular design of tent, i.e., that of Fischell, as the stent mentioned on page 6, line 6-10 of Caro. Even if one skilled in the art were to make a device based on that combination, he/she would still have a stented tubing for use as a prosthesis, not a stent for insertion in an intact blood vessel, as required by claim 24. Nor would one have any suggestion that the stented tubing would be suitable for such a use.

Moreover, Fischell discloses a cylindrical stent used to create and maintain the patency of an intact vessel (column 1, lines 5-7). The stent is designed to have radial rigidity, i.e., to prevent collapse or kinking (see column 1, lines 32-33). It is, however, also designed to be longitudinally flexible during deployment to allow for easier placement through highly curved coronary arteries (column 1, lines 33-35 and column 3, lines 9-12). The natural shape of the stent is cylindrical (column 2, lines 44-46, lines 56-57 and claim 1), and any longitudinal flexing from this shape occurs because the vessel (artery) imposes a longitudinal curvature on the stent. This is the reverse of the requirement of claim 24 of the present application, wherein the stent imposes a longitudinal curvature on the vessel, in particular a non-planar curve.

Thus, while the Fischell stent might be able to reinforce the Caro tubing to prevent collapse or kinking (“radial rigidity” as distinct from longitudinal flexibility – see column 1, lines 31-35 of Fischell), the tubing wall would have to hold the stent in the desired non-planar curve, rather than allowing the stent to return to its natural cylindrical shape. This may be a possibility when the tubing is used as a vascular prosthesis, as taught in Caro, but the applicants respectfully submit that it is doubtful whether such a stented tubing would be able to impose a non-planar curve on an intact vessel. Neither

the tubing of Caro nor the stent of Fischell are disclosed as having this capability. This teaching remains absent from both Caro and Fischell.

Accordingly, for the reasons set forth above, Caro and Fischell fail to teach or suggest all the claim limitations of independent claim 24 and, consequently, claims dependent or ultimately dependent from claim 24.

**VII. The Rejection of Claim 31 Under 35 U.S.C. §103(a) Has Been Overcome**

For the reasons set forth above, the references cited by the Examiner fail to teach or suggest all the claim limitations of independent claim 24 and, consequently, claims dependent or ultimately dependent from claim 24. For at least this reason, the cited references do not render claim 31 dependent therefrom obvious.

**VIII. The Rejection of Claims 12-16 Under 35 U.S.C. §103(a) Has Been Overcome**

For the reasons set forth above, the references cited by the Examiner fail to teach or suggest all the claim limitations of independent claim 24 and, consequently, claims dependent or ultimately dependent from claim 24. For at least this reason, the cited references do not render claims 12-16 dependent therefrom obvious.

**VIII. New Claim 42**

Regarding new claim 42, this claim further strengthens applicants' position regarding novelty. As recited in claim 42, the stent is placed *in situ* in the intact vessel. Such a stent, placed within an intact vessel, is entirely different from the stented tubing used as a prosthesis, as disclosed in Caro. Caro simply does not disclose a stent in place in an intact vessel. As such, new claim 42 is not anticipated by Caro.

Further, the Examiner's proposed use of a Fischell stent to reinforce a Caro tubing still remains a vascular prosthesis, not a stent in an intact vessel. Hence the subject-matter of the new claim is not remotely suggested nor rendered obvious by the combination Caro and Fischell.

**CONCLUSION**

For the reasons detailed above, it is respectfully submitted that all claims remaining in the application (Claims 3, 5, 6, 12-16, 24-31 and 42) are now in condition for allowance. The foregoing comments do not require unnecessary additional search or examination.

No additional fee is believed to be required for this Amendment. If, however, a fee is due, the Commissioner is authorized to charge our Deposit Account No. 06-0308.

In the event the Examiner believes a telephone call would expedite prosecution, he is invited to call the undersigned.

Respectfully submitted,

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12 July 2004  
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Certificate of Mailing

Under 37 C.F.R. § 1.8, I certify that this Amendment is being deposited with the United States Postal Service as First Class mail, addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date
July 12, 2004

Signature
<u>Kathleen A. Nimrichter</u>
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